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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,915	10/27/2006	Claus Justus	2508.0010000	1315

26111 7590 08/01/2011

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EXAMINER	
WHITE, ESTEBAN A	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
08/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,915	JUSTUS, CLAUS	
	Examiner	Art Unit	
	ESTEBAN WHITE	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Abstract

The abstract of the disclosure is objected to because the abstract is greater than one paragraph and greater than 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 6 objected to because of the following informalities: The word "utilizes" is misspelled. It is suggested that the application in its entirety be reviewed for additional errors. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claims 19—23 are rejected under 35 USC 112 4th paragraph, as being an improper dependent claim for failing to include all the limitations of the claim upon which it depends and for failing to further limit the subject matter of the claim upon which it depends.

Claims 19—23 are drawn to method claims and do not include all the limitations of the apparatus of claim 1 upon which they refer to. It is unclear whether applicant intends the claim is a method claim or apparatus claim.

In regards to compact prosecution, the Examiner is interpreting claims 19—23 to be apparatus steps dependent on claim 1 as presented in the original disclosure. As the Federal

Circuit treats non-compliance with 35 USC 112 4th paragraph as a patentability issue, it is considered more appropriate to treat a claim that does not comply with 35 USC 112 4th paragraph by rejecting the claim under 35 USC 112 4th rather than by objecting to such claim under 37 CFR 1.75(c) as provided for in MPEP 608.01(n)(II). See *Pfizer Inc. v. Ranbaxy Labs., Ltd.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006). Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1—9, 11, and 13—23 are rejected under 35 U.S.C. 102(a) as being anticipated by Verlinden et al., International Application Publication number WO 03/038727 A2.

Regarding claim 1, Verlinden et al. discloses a diagnostic tool *(Abstract, an expert system for medical diagnosis)* adapted to assist in the diagnosis of pulmonary diseases, based on data not including lung function measurement data, comprising:

a display unit *(Fig. 1, item 3)* for displaying predefined diagnostic questions relating to the pulmonary disease, and for outputting a diagnostic prognosis on the disease (*Page 8, line 15 where output (3) enables the system to represent the stored questions to a user. The output is*

also used for giving diagnoses, conclusions to a user and/or human expert. The output may take any suitable form, such as a display for displaying the questions and answers provided by the user),

input unit *(Fig. 1, item 4)* adapted to receive responses from a user to the diagnostic questions displayed on the display unit *(Page 8, line 23 where the input may take the form of a keyboard for receiving the initial data, such as medical complaint, and/or personal data including age, gender, sex, and (if desired) name, address, medical insurance number, etc. The input may also be in other forms, such as handwriting (e.g. using a Personal Digital Assistant as input device),*

a storage unit *(Fig. 1, item 2)* having stored thereon the predefined questions and the interactively input responses *(Page 8, line 13 where the system includes a storage for storing a collection of questions),*

and a calculation unit *(Fig. 1, item 5 and page 9, line 5 where the system also includes a processor that under control of a suitable program, controls the additional functions of the system, such as the input and output, and provides the core functionality of the expert system)* adapted to:

assign each received response a predetermined count value *(Page 15, where the processor assigns values to inputs by the end user and places each value in a table),*

add up the count values obtaining a final count value *(Page 12 where the "likelihood" may be given as a percentage, but it may also take any other suitable form that enables the system to rank the hypotheses (e.g. a sequential number, or a choice from options, like small, average, high. Also, page 18, line 13 where the "likelihood" is defined as a weighted value),*

and assign the final count value the diagnostic prognosis using a predefined result table stored in the storage unit *(See tables on page 11 and 15).*

Regarding claim 2, Verlinden et al. discloses the diagnostic tool of claim 1, wherein the diagnostic prognosis is given as a percentage value for the general practitioner or a risk factor for the patient *(Page 12 where the "likelihood" may be given as a percentage, but it may also take any other suitable form that enables the system to rank the hypotheses (e.g. a sequential number, or a choice from options, like small, average, high).*

Regarding claim 3, Verlinden et al. disclose the diagnostic tool of claims claim 1, wherein the diagnostic questions comprise questions about patient demographic data, smoking status and subjective patient disease symptoms *(Page 5, line 15—30 where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). Also, page 6, line12—17 where the system can retrieve data from a medical record storing system and use data from this record for its operations and/or store data in the medical record. Preferably, this includes using the data to retrieve answers to question(s) of the question set being tested. Lastly, page 8, line 23 where the input may take the form of a keyboard for receiving the initial data, such as medical complaint, and/or personal data including age, gender, sex, and (if desired) name, address, medical insurance number, etc. The input may also be in other forms, such as handwriting (e.g. using a Personal Digital Assistant as input device).*

Regarding claim 4, Verlinden et al. disclose the diagnostic tool of claim 3, wherein the demographic data include age, sex and/or body mass index (BMI) of the patient *(Page 8, line 23 where the input may take the form of a keyboard for receiving the initial data, such as medical complaint, and/or personal data including age, gender, sex, and (if desired) name, address, medical insurance number, etc. The input may also be in other forms, such as handwriting (e.g. using a Personal Digital Assistant as input device). It is anticipated that the system can also request and store information on the BMI—information which would normally be found in the medical record of the patient (page 6, line12—17 where the system can retrieve data from a medical record storing system and use data from this record for its operations and/or store data in the medical record).*

Regarding claim 5, Verlinden et al. disclose the diagnostic tool of claim 3, wherein the questions about the smoking status of the patient include questions about current smoking status and aggregate smoking history *(Page 5, line 15—30 where In a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD).*

Regarding claim 6, Verlinden et al. disclose the diagnostic tool of claim 5, wherein the calculation unit utilizes a transformation table assigning predetermined count values to different combinations of smoking intensity (cigarettes per day) and smoking duration (in years) *(Page 5, line 15—30 where, in a preferred embodiment, the system can share questions between*

hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). It is anticipated that the expert system will construct a table—such as that on page11 and 15—for the purpose of evaluating a patient who suffers from COPD.

Regarding claim 7, Verlinden et al. discloses the diagnostic tool of one of claim 3, wherein the subjective patient disease symptoms include breathing restrictions, phlegm and chest wheezing or whistling *(Page 3, lines 15—30 where the expert system is able to rule out maladies including asthma, pneumonia, chronic bronchitis, emphysema, whooping cough and heart failure. Also, Page 5, line 15—30 where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). Lastly, page 15 where the expert system is able to differentiate between the colors of nasal mucus. It is anticipated that questions regarding breathing restrictions, phlegm, chest wheezing and whistling are presented to the user in order to rule out the aforementioned conditions.*

Regarding claim 8, Verlinden et al. discloses the diagnostic tool of one of claim 1, wherein the diagnostic tool is formed as an electronic instrument *(Page 8, line 27 and page 9, line 1 where the expert system is found to be in the form of a PDA or mobile phone respectively).*

Regarding claim 9, Verlinden et al. discloses the diagnostic tool of claim 8, being formed as a handheld device comprising an input key (4) and a scroll wheel (4a) allowing one hand operation of the diagnostic tool *(Page 8, line 27 and page 9, line 1 where the expert system is found to be in the form of a PDA or mobile phone respectively).*

Regarding claim 11, Verlinden et al. discloses the diagnostic tool of claim 8, wherein the diagnostic tool is integrated with a handheld computer or organizer *(Page 8 line 27 where the expert system is found to be in the form of a PDA).*

Regarding claim 13, Verlinden et al. discloses the diagnostic tool of one of claim 1, being formed as a mechanical device *(See fig. 1, and page 8 line 27 and page 9, line 1 where the expert system is found to be in the form of a PDA or mobile phone respectively).*

Regarding claim 14, Verlinden et al. discloses the diagnostic tool of claim 1 which can be operated in remote application, as for example by Internet, by Email, SMS or *MMS (Page 9, line 2 where the output/input may be separate from the main part (20). For, example, a patient may operate the system from a different location, e.g. through a personal computer or mobile phone. Such a remote terminal is indicated using number (10). The main part (20) and the terminal (10) may exchange data in any suitable form, e.g. via local or wide area communication based on wired or wireless technology. To this end, any suitable protocol may be used, such as SMS, WAP, GPRS, UMTS, Ethernet, etc).*

Regarding claim 15, Verlinden et al. discloses the diagnostic tool of claim 1, wherein the diagnostic tool is used for diagnosing chronic obstructive pulmonary disease (COPD) *(Page 5, line 15—30 where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses.*

As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD).

Regarding claim 16, Verlinden et al. discloses the diagnostic tool of claim 1, wherein the diagnostic tool is used for diagnosing previously undiagnosed persons *(Page 1, line 13 where it is an object of the invention to provide a user friendly expert system, in particular a medical diagnosis system, that with a limited number of interactions with a user, can confirm a hypothesis (e.g. make a diagnosis) without risking overlooking hypotheses that may not be taken by the system or cannot be taken with the limited number of interactions. Further, in instances where the expert system is unable to provide a likely diagnosis, it refers you to the care of a General Practitioner (Page 14, lines 5—11).*

Regarding claim 17, Verlinden et al. discloses the diagnostic tool of claim 1, wherein the diagnostic tool is used as a tool for the recruitment of participants for clinical trials *(Page 14, lines 5—11 where If all hypotheses have been rejected, the most likely hypothesis of the first group may be issued to the user. Otherwise, testing can stop as soon as one hypothesis of the second group is likely or can not be ruled out by the system. In this case, no diagnosis can be issued. Instead, the system may recommend the user to consult a medical expert or automatically transfer the interaction to the medical expert (or arrange that an appointment with the medical expert is made). The question sets may be issued in decreasing likelihood of the associated hypothesis (i.e. starting with the most likely one and ending with the least likely one). It is anticipated that such information is used as a tool for recruitment of participants for clinical trials.*

Regarding claim 18, Verlinden et al. discloses the diagnostic tool of claim 1, wherein the diagnostic tool is used as a differential diagnosis tool allowing to differentiate COPD from other chronic obstructive respiratory diseases such as asthma *(Page 5, line 15—30 where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). Also, see page 3, lines 15—30 where the expert system is able to rule out maladies including asthma, pneumonia, chronic bronchitis, emphysema, whooping cough and heart failure).*

Regarding claim 19, Verlinden et al. discloses a method of diagnosing chronic obstructive pulmonary disease (COPD) in a person, wherein the method comprises the input and evaluation of responses from said person with the aid of a diagnostic tool of claim 1 *(Abstract, where an input (4) is used for receiving initial data and answers to questions. A processor (5) is programmed to select questions from the stored questions for those hypotheses from the second group that are possible in dependence on the initial data. The processor also determines from answer(s) received in response to outputting the selected questions whether at least one of the hypotheses of the second group is possible. In response to determining that no hypothesis of the second group is possible, the processor supplies a most likely hypothesis of the first group).*

Regarding claim 20, Verlinden et al. discloses a method of diagnosing COPD in a previously undiagnosed person, wherein the method comprises the input and evaluation of responses from said person with the aid of a diagnostic tool of claim 1 *(Page 5, line 15—30*

where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). Also, see page 3, lines 15—30 where the expert system is able to rule out maladies including asthma, pneumonia, chronic bronchitis, emphysema, whooping cough and heart failure).

Regarding claim 21, Verlinden et al. discloses a method for the recruitment of participants for clinical trials, wherein the method comprises the input and evaluation of responses from potential participants with the aid of a diagnostic tool of claim 1 *(Page 14, lines 5—11 where If all hypotheses have been rejected, the most likely hypothesis of the first group may be issued to the user. Otherwise, testing can stop as soon as one hypothesis of the second group is likely or can not be ruled out by the system. In this case, no diagnosis can be issued. Instead, the system may recommend the user to consult a medical expert or automatically transfer the interaction to the medical expert (or arrange that an appointment with the medical expert is made). The question sets may be issued in decreasing likelihood of the associated hypothesis (i.e. starting with the most likely one and ending with the least likely one).*

Regarding claim 22, Verlinden et al. discloses a method to differentiate COPD from other chronic obstructive respiratory diseases, wherein the method comprises the input and evaluation of responses from a person with the aid of a diagnostic tool of claim 1 *(Page 5, line 15—30 where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example,*

the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). Also, see page 3, lines 15—30 where the expert system is able to rule out maladies including asthma, pneumonia, chronic bronchitis, emphysema, whooping cough and heart failure).

Regarding claim 23, Verlinden et al. discloses a method to differentiate COPD from asthma, wherein the method comprises the input and evaluation of responses from a person with the aid of a diagnostic tool of claim 1 *(Page 5, line 15—30 where in a preferred embodiment, the system can share questions between hypotheses. This enables using an already received answer also for evaluating other hypotheses. As an example, the specific symptom cough in combination with the fact that this occurs 3 times or more a year in a person who is over the age 40 and who smokes, makes it very likely that this person suffers from Chronic Obstructive Pulmonary Disease (COPD). Also, see page 3, lines 15—30 where the expert system is able to rule out maladies including asthma, pneumonia, chronic bronchitis, emphysema, whooping cough and heart failure).*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10 is rejected under 35 U.S.C. 103(a) as obvious over Verlinden et al., International Application Publication number WO 03/038727 A2, in view of Leem et al., International Patent Application Publication WO 01/65711 A1.

Regarding claim 10, Verlinden et al. discloses the diagnostic tool of claim 8, but does not disclose the limitation where the device comprises photovoltaic cells as power source.

Leem et al., however, teaches this limitation as a mobile terminal having a solar cell, which is capable of providing sufficient electric power to the mobile terminal *(Abstract and fig. 1).*

Therefore, it would have been obvious to one of ordinary skill in the art having the teachings of Verlinden et al., and Leem et al. at the time the invention was made to modify Verlinden et al. with a PDA or mobile phone comprising a photovoltaic cell as a power source as taught by Leem et al.

Claim 12 is rejected under 35 U.S.C. 103(a) as obvious over Verlinden et al., International Application Publication number WO 03/038727 A2, in view of Yaski et al., U.S. Patent Application Publication US 2001/0040109 A1.

Regarding claim 12, Verlinden et al. discloses the diagnostic tool of claim 8, but does not disclose the limitation wherein the diagnostic tool comprises a casing for housing a prescription pad (21) and a pen.

Yaski et al., however, teaches this limitation as a hollow rectangular case made of resilient material having an upper half and a lower half. The case having a compartment for an electronic device, a writing utensil and a pad *(Fig. 1).*

Therefore, it would have been obvious to one of ordinary skill in the art having the teachings of Verlinden et al., and Yaski et al., at the time the invention was made to modify Verlinden et al. with a casing for housing the expert system for medical diagnosis, a prescription pad and a pen as taught by Yaski et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ESTEBAN WHITE whose telephone number is (571)270-5801. The examiner can normally be reached on Monday thru Thursday 7:00 am to 5:30 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Miranda Le can be reached on (571) 272-4112. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ESTEBAN WHITE/
Examiner, Art Unit 3735

/Miranda Le/
Supervisory Patent Examiner, Art Unit 3735